Dewey & LeBoeuf LLP
1101 New York Avenue, NW
Washington, DC 20005-4213

T +1 202 346 8000
F +1 202 346 8102

DEWEY & LEBOEUF

This material is being distributed by Dewey & LeBoeuf LLP on behalf of the Saudi Food and Drug Authority. Additional information is on file with the U.S. Department of Justice in Washington, DC

November 8, 2011

VIA OVERNIGHT COURIER

Dr. Beth P. Bell, MPH
Director
National Center for Emerging and Zoonotic Infections
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333

Dear Dr. Bell:

We represent the Saudi Food and Drug Authority ("SFDA") in connection with a United States Food and Drug Administration ("US FDA") matter that concerns, among other things, country attribution of three cases of variant Creutzfeldt-Jakob Disease. We are seeking information regarding two of these cases that were diagnosed in the United States. We understand that one of these cases – as identified in the attached issue summary prepared by the Transmissible Spongiform Encephalopathies Advisory Committee ("TSE Committee") – was diagnosed at the Mayo Clinic and confirmed by the National Prion Disease Pathology Surveillance Center at Case Western Reserve University (which was founded and is currently supported by the CDC). The other – also described in the attached issue summary – was diagnosed by the UCSF Hospital at the University of California in San Francisco and referred to the Surveillance Center.

The SFDA has requested this information from the US FDA and, while the US FDA has not declined the request, the SFDA has not yet received the information. The SFDA has not asked the Surveillance Center for this information directly because of concerns that the Surveillance Center will deny disclosure of this information to the SFDA based on a belief that the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prevents such disclosure.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

We believe that disclosure of this information is "excepted" from HIPAA as a "public health activity." More specifically, we believe that disclosure to the SFDA would be permitted at the direction of the CDC (or the US FDA) to the Surveillance Center under 145 C.F.R. 164.512(b)(1)(i) , which allows disclosure of HIPAA-protected information at the direction of a United States public health authority to a foreign government agency that is acting in collaboration with a United States public health authority.[1] As noted above, the SFDA is working with the US FDA on this issue and therefore such a request would clearly come within this exception. In addition, we note that the Saudi Arabia Ministry of Health has signed a Memorandum of Understanding with the United States Health and Human Services (copy attached) that specifically calls for cooperation between the United States and Saudi Arabia respecting, among other things, public health (including epidemiology and disease surveillance). A direction to the Surveillance Center to disclose this information to the SFDA would be consistent with the Memorandum of Understanding.

On behalf of the SFDA, we thus request that the CDC direct the Surveillance Center to disclose this information to

Ziad Memish, MD, FACP, FRCPC, FIDSA
Assistant Deputy Minister of Health
Preventive Medicine Directorate
Ministry of Health
Riyadh 11176
Kingdom of Saudi Arabia

Because we believe that a direction from either the CDC or the US FDA appropriately triggers the public health activity exception described above, we also have requested that the US FDA direct the Surveillance Center to disclose this information.

---

[1] 145 C.F.R. 164.512(b)(1)(i) provides, in relevant part (emphasis added), as follows:

(b) Standard: Uses and disclosures for public health activities.

(1) Permitted disclosures. *A covered entity may disclose protected health information for the public health activities and purposes* described in this paragraph to

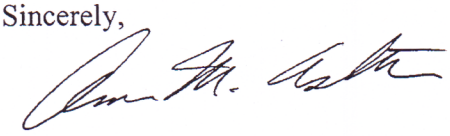
(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, *at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority* . . . .

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Receipt of the requested information is very important to the SFDA's being able to address the appropriateness of attributing the two described vCJD cases to Saudi Arabia and thus prompt receipt of the information is imperative. With that in mind, we have taken the liberty of preparing a draft letter to the Surveillance Center from the CDC directing disclosure of the information to the SFDA.

Please do not hesitate to contact me if you have any questions or require any additional information.

Sincerely,



Ann M. Ashton

Cc: Stephan S. Monroe, Ph.D.
Director
Division of High-Consequence Pathogens and Pathology
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Protection

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

CDC Letterhead

November __, 2011

Dr. Pierluigi Gambetti
Director
National Prion Disease Pathology Surveillance Center
Institute of Pathology
Division of Neuropathology
Case Western Reserve University
2085 Adelbert Road
Cleveland, Ohio 44106-4907

Dear Dr. Gambetti:

The Saudi Food and Drug Authority ("SFDA") is currently involved in a proceeding with the United States Food and Drug Administration ("US FDA") that involves, among other things, attribution of two cases of variant Creutzfeldt-Jakob Disease to Saudi Arabia. The cases are described in an issue summary prepared by the US FDA's Transmissible Spongiform Encephalopathies Advisory Committee as follows:

> An earlier case of vCJD in 2003, never described in detail, affected a 33-year old Saudi citizen who underwent brain biopsy at a hospital in Saudi Arabia; vCJD was diagnosed from a sample of the biopsy sent to the Mayo Clinic, Rochester, Minnesota, and confirmed by the National Prion Disease Surveillance Center, Case Western Reserve University, Cleveland, Ohio.
>
> One previous case of vCJD, diagnosed by brain biopsy at the UCSF Hospital, University of California, San Francisco, and briefly described by the CDC, occurred in a person living in Virginia who was a non-Saudi Arabian national born and raised in Saudi Arabia. That person's family recalled no history of travel to UK except for connecting flights.

The SFDA is requesting all information regarding the individuals involved in these cases, including the information relied upon in attributing the cases to Saudi Arabia.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

The CDC has determined that the SFDA's request for this information falls within the public health activity exception to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") found at 145 C.F.R. 164.512(b)(1)(i), which provides for disclosure "at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority."

The CDC therefore directs the Center to provide the SFDA with the complete record underlying the diagnosis of these two case of vCJD, including all information available about the individuals involved. This disclosure should be made promptly to

Ziad Memish, MD, FACP, FRCPC, FIDSA
Assistant Deputy Minister of Health
Preventive Medicine Directorate
Ministry of Health
Riyadh 11176
Kingdom of Saudi Arabia

If you have any questions, please do not hesitate to call _____ at _____.

Sincerely,

_____

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

MEMORANDUM OF UNDERSTANDING FOR COOPERATION BETWEEN THE MINISTRY OF HEALTH IN THE KINGDOM OF SAUDI ARABIA AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IN THE UNITED STATES OF AMERICA IN THE FIELD OF PUBLIC HEALTH AND MEDICAL SCIENCES

The Ministry of Health in the Kingdom of Saudi Arabia and the Department of Health and Human Services in the United States of America "hereinafter referred to as the Two Participants," understanding the benefit of unified efforts to address issues of public health and medical and scientific challenges of mutual concern; desiring to foster and strengthen relationships between the Two Participants and understanding the importance of working together in solving common health issues, realizing the mutual interest of the Two Participants in the field of prevention of diseases and promotion of health; and desiring to strengthen the existing ties between the medical and research institutions in both countries in the fields of public health and medical sciences;

Have reached the following understandings:

مذكرة تفاهم
بين
وزارة الصحة في المملكة العربية السعودية
ووزارة الصحة والخدمات الإنسانية في الولايات المتحدة الأمريكية

للتعاون في مجالي الصحة العامة والعلوم الطبية

إن وزارة الصحة في المملكة العربية السعودية ووزارة الصحة والخدمات الإنسانية في الولايات المتحدة الأمريكية، المشار إليهما فيما بعد "بالمشاركين"،

إدراكا منهما لفائدة توحيد الجهود لمواجهة قضايا الصحة العامة والتحديات الطبية والعلمية ذات الاهتمام المشترك،

ورغبة منهما في تشجيع تعزيز وتقوية العلاقات بين المشاركين وإدراكا منهما لأهمية العمل معاً في حل المشاكل العامة للصحة، وإدراكا منهما لوجود اهتمامات مشتركة بينهما في مجال الوقاية من الأمراض وتعزيز الصحة، ولرغبة المشاركين في تقوية الروابط القائمة بين المؤسسات الطبية والبحثية في البلدين في مجالات الصحة العامة والعلوم الطبية،

فقد اتفقا على ما يلي:

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Section 1: General Principles

The Two Participants intend to strengthen cooperation in health fields according to the following principles:

1- The purpose of cooperation under this Memorandum of Understanding (MOU) is to support and strengthen existing relationships in the fields of public health among individuals, organizations, and institutions of both Participants.

2-The Participants intend to specify cooperation areas of mutual interest.

3-Joint activities between the Two Participants should be carried out through coordination with international health organizations, such as the World Health Organization.

Section 2: Areas of Cooperation

The Two Participants intend to strengthen cooperation between them in areas of joint interest, which may include, for example, the following:

1-Health information systems, including proper application of information science and technology, capacity building strategy; standards and information systems for routine disease surveillance, laboratories, medical care, health surveys, emergency, outbreak investigations, and mass gatherings;

2-Human resources, including capacity building in the areas of delivery of health services, public health systems, academic and scientific training on government and private levels, cooperation in training pertaining to the Saudi field epidemiology program, and improving surveillance of communicable and non-communicable diseases.

القسم الأول: المبادئ العامة:

ينوي المشاركان تعزيز التعاون في المجالات الصحية وفقاً للمبادئ الآتية:

١- يهدف التعاون بموجب هذه المذكرة إلى دعم وتقوية العلاقات القائمة حالياً في مجالات الصحة العامة فيما بين الأفراد والمنظمات والمؤسسات لدى المشاركين.

٢- ينوي المشاركان تحديد المجالات ذات الاهتمام المشترك للتعاون بينهما.

٣- ينبغي تنفيذ الأنشطة المشتركة بين المشاركين بالتنسيق مع المؤسسات الصحية الدولية، مثل منظمة الصحة العالمية.

القسم الثاني: مجالات التعاون:

ينوي المشاركان تعزيز التعاون فيما بينهما في مجالات الاهتمام المشترك التي قد تشمل، على سبيل المثال ما يلي :-

١- نظم المعلومات الصحية، وتشمل التطبيق السليم لعلم وتقنية المعلومات، وإستراتيجية بناء القدرات، والمعايير وأنظمة المعلومات للرصد الروتيني للأمراض، وللمختبرات، والعناية الطبية، والاستبيانات الصحية، والطوارئ، والتحري في حالات تفشي الأمراض، وتجمعات الجماهير البشرية.

٢- الموارد البشرية، وتشمل بناء القدرات في مجالات تقديم الخدمات الصحية، ونظم الصحة العامة، والتدريب الأكاديمي والعلمي على المستوى الحكومي والخاص، والتعاون في مجال التدريب الخاص ببرنامج الوبائيات الحقلي السعودي، وتحسين رصد ومراقبة الأمراض المعدية وغير المعدية.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

3-Public health including epidemiology, disease surveillance, communicable diseases, zoonosis, chronic diseases (risk factors related to chronic diseases), disaster preparedness and management, nutrition, maternal and child health, congenital deformities, preventive health, and health promotion;

٣- الصحة العامة وتشمل الوبائيات، ورصد ومراقبة الأمراض، والأمراض المعدية، والأمراض المشتركة بين البشر والحيوانات، والأمراض المزمنة (عوامل الخطورة المتصلة بالأمراض المزمنة) والاستعداد المبكر لمجابهة الكوارث والسيطرة عليها، والتغذية، وصحة الأم والطفل، والعيوب الخلقية، والصحة الوقائية، وتعزيز الصحة.

4-Health-related concerns of women and special needs populations, including the elderly, the disabled, teenagers, children and other vulnerable groups;

٤- الاهتمامات الصحية الخاصة بالمرأة والمجموعات السكانية ذات الاحتياجات الخاصة، بمن فيهم كبار السن والمصابين بعجز ما، والمراهقين والأطفال والفئات الأخرى المعرضة للخطر.

5-Health services research, including assessment of health care technologies, health services delivery systems, health services financing, health care cost containment; and public health intervention;

٥- بحوث الخدمات الصحية، بما في ذلك تقييم تقنيات الرعاية الصحية ونظم تقديم الخدمات الصحية، وتمويل الخدمات الصحية، واحتواء تكاليف الرعاية الصحية، وأعمال التدخل في سبيل الصحة العامة.

6-Diseases and health conditions of special interest, such as pathogens, particularly influenza;

٦-الأمراض والظروف الصحية المثيرة للاهتمام الخاص، مثل مسببات الأمراض، وخاصة الأنفلونزا.

7-Public policies oriented to disease prevention and health promotion;

٧- السياسات العامة الموجهة لأغراض الوقاية من الأمراض وتعزيز الصحة.

8-Biomedical and behavioral research; and

٨- البحوث الطبية الحيوية والأبحاث السلوكية

9-Any other area as mutually identified by the Two Participants.

٩- أي مجال آخر يحدده المشاركان بصورة مشتركة.

Section 3: Methods of Cooperation

Cooperation under this MOU may be carried out through any of the following methods:

القسم الثالث: أسلوب التعاون:

يجوز تنفيذ التعاون بين المشاركين بموجب هذه المذكرة عن طريق أي من الأساليب التالية:

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

١ - تبادل المعلومات

٢ - تبادل الخبراء والأكاديميين

٣- تدريب القوة العاملة الصحية والطبية السعودية

٤ - إجراء البحوث المشتركة

٥- عقد المؤتمرات والندوات

٦ - أي أسلوب آخر يحدده المشاركان بصورة مشتركة.

يسعى المشاركان في سبيل تعزيز العلاقات والروابط المباشرة بين المؤسسات والأفراد في البلدين، حسب الحاجة، بغية تعزيز التعاون في مجالات الصحة العامة والعلوم الطبية.

القسم الرابع: تنظيم التعاون:

١-تقوم الإدارة العامة للعلاقات الدولية بوزارة الصحة في المملكة العربية السعودية ومكتب الشؤون الصحية العالمية بوزارة الصحة والخدمات الإنسانية بالولايات المتحدة بدور المنسقين العامين للتعاون في إطار هذه المذكرة، وتحدد مجالات التعاون الواردة في (القسم الثاني) من هذه المذكرة وفقاً للأولويات التي يحددها المشاركان بصورة مشتركة.

٢- على من يقوم بمهام المنسق لدي كل من المشاركين تحديد منسق إداري له يتولى الإشراف على التنفيذ العملي للأنشطة المذكورة في هذه المذكرة، ويجوز للمشاركين تشكيل لجان عمل مشتركة من الخبراء والاختصاصيين لمتابعة تنفيذ هذه المذكرة، ويجوز لهذه اللجان أن تجتمع بحسب الحاجة.

1-Exchange of information.

2-Exchange of experts and academicians.

3-Training Saudi health and medical workforce.

4-Conducting joint research.

5-Holding conferences and seminars.

6-Any other method as mutually identified by the Two Participants.

The Two Participants endeavor to promote relations and direct ties between institutions and individuals in both countries as needed, so as to enhance cooperation in areas of public health and medical sciences.

Section 4: Regulating Cooperation

1. The General Directorate of International Relations in the Ministry of Health in the Kingdom of Saudi Arabia and the Office of Global Health Affairs in the Department of Health and Human Services in the United States of America are to act as the coordinators for cooperation within the framework of this MOU. Areas of cooperation provided for in Section 2 of this MOU are to be specified in accordance with the priorities mutually determined by the Two Participants.

2. The coordinator of each Participant is to name an administrative coordinator to oversee the implementation of activities set out in this MOU. The Two Participants may form joint working committees of experts and specialists from both sides to follow up on the implementation of this MOU. Said committees may convene as necessary.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Section 5: Financial Aspects and Disclaimer

1 Activities carried out under this MOU are to be conducted in accordance with the applicable laws and regulations in both countries.

2-Activities carried out under this MOU are to be subject to the discretion of each Participant and are to be subject to the availability of appropriated funds.

3 -Each Participant is to bear the costs of its own participation. Funding arrangements for specific activities may be made by mutual determination of the Two Participants.

4-This MOU is not an international agreement and does not give rise to rights or obligations under international law.

Section 6: Commencement, Discontinuation, and Modification

1. This MOU is to become effective on the date of signature by both Participants. It is to remain valid for two years, and the Participants may review and mutually decide to continue their cooperation before that period ends.

2. The Two Participants may, at any time, modify this MOU by mutual, written consent.
3. Either Participant may, at any time, discontinue its cooperation under this MOU, and should endeavor to notify the other party thereof, in writing, at least six months in advance of its intent to discontinue its participation.

القسم الخامس: النواحي المالية وتوضيح المسئوليات:

١- تُمارس الأنشطة التي تُنفذ في إطار هذه المذكرة وفقاً للأنظمة واللوائح المطبقة في البلدين.

٢- تخضع الأنشطة التي تُمارس في إطار هذه المذكرة لتقدير كل من المشاركين وما يرتئيه كل منهما، كما تخضع هذه الأنشطة للمتاح من المخصصات المالية.

٣- يتحمل كل من المشاركين تكاليف مشاركته الخاصة في هذه الأنشطة، ويجوز للمشاركين اتخاذ ترتيبات لتمويل أنشطة محددة يتم تحديدها فيما بينهما بصورة مشتركة.

٤- إن مذكرة التفاهم هذه ليست اتفاقا دوليا، ولا يترتب عليها نشوء حقوق أو واجبات بموجب القانون الدولي.

القسم السادس: دخول المذكرة حيز النفاذ وإنهاء العمل بها وتعديلها:

١- من المقرر أن تدخل هذه المذكرة حيز النفاذ اعتباراً من تاريخ توقيع المشاركين عليها، وأن تظل سارية المفعول لمدة سنتين، ويجوز للمشاركين المراجعة عليها واتخاذ قرارا مشتركا بمواصلة التعاون فيما بينهما قبل انتهاء هذه المدة.

٢- يجوز للمشاركين تعديل مذكرة التفاهم هذه بموجب موافقة مكتوبة على ذلك من كليهما.

٣- يجوز لأي من المشاركين أن يقوم في أي وقت بإنهاء تعاونه مع المشارك الآخر في إطار هذه المذكرة، وينبغي عليه أن يسعى لإشعار الطرف الأخر بذلك كتابة، قبل حلول تاريخ إنهاء التعاون بستة شهور.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

4. In case of discontinuation of this MOU, its provisions are to remain valid for joint programs until completed.

٤- في حال إنهاء العمل بهذه المذكرة، تستمر أحكامها نافذة بالنسبة إلى البرامج المشتركة حتى الانتهاء من تنفيذ هذه البرامج.

Signed in Geneva, Switzerland on dated / / 14, and corresponding to May 18/2014, in duplicate, in the Arabic and English languages. All the texts shall be equally binding.

تم التوقيع على هذه المذكرة في مدينة (جنيف) بسويسرا يوم الثلاثاء بتاريخ ١٤/٧/١٤٣٥ هـ الموافق ١٨/٥/٢٠١٤م، وقد تم التوقيع على نسختين أصليتين، باللغتين العربية والإنجليزية، والنصان متساويان في الحجية.

FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES IN THE UNITED STATES OF AMERICA

Kathleen Sebelius

THE MINISTRY OF HEALTH IN THE KINGDOM OF SAUDI ARABIA

عن وزارة الصحة بالمملكة العربية السعودية

عن وزارة الصحة والخدمات الإنسانية، الولايات المتحدة الأمريكية

Kathleen Sebelius

FDA Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC)
23rd Meeting, August 1, 2011
Gaithersburg, MD

Issue Summary

Donor Deferral/Ineligibility for Time Spent in Saudi Arabia to Reduce Risk of vCJD Transmitted by Blood and Blood Products and by Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)

Issue

FDA seeks advice from TSEAC on whether, based on three cases of vCJD in individuals likely to have been infected with the BSE agent in Saudi Arabia, to modify current vCJD-related safety recommendations for donors of blood and blood components, including Source Plasma, and for donors of HCT/Ps, to recommend deferring of certain blood donors or finding ineligible certain donors of HCT/Ps for time spent in Saudi Arabia.

Background

vCJD in recent Saudi immigrant to Canada. In March 2011 Health Canada described a probable case of vCJD in a recent immigrant. The diagnosis of vCJD was supported by results of a tonsil biopsy in Canada showing accumulation of abnormal prion protein [26]. The patient is a young man, born in 1986, who spent most of his early life in Saudi Arabia (12 yr) and, later, in neighboring Dubai, United Arab Emirates (4 yr) [4, 11]. He first showed symptoms of vCJD early in 2011 before emigrating from Dubai to Canada. The probable time of food-borne infection with the BSE agent for individuals with the patient's prion-protein-encoding (*PRNP*) genotype (129MM) falls within the years he lived in the Arabian Peninsula (estimated median incubation period of food-borne vCJD for persons with the *PRNP*-129-MM genotype, estimated to be 12 to 13 yr [1, 18]). Authorities at Health Canada [19] have concluded that the man, who has no history of surgery or blood transfusion, was probably infected by dietary exposure to the BSE agent while in the Arabian Peninsula, more likely in Saudi Arabia, where he spent most of his early years, than in Dubai. It is much less likely, though not impossible, that he might have been exposed to the BSE agent during a visit of two weeks to the UK in 1995 (near the end of the UK BSE dietary risk period). He paid a second brief visit to the UK in 2002, six years after the UK dietary risk period is thought to have ended [25]. This is the third case of vCJD plausibly attributed to a dietary exposure to BSE agent in Saudi Arabia.

vCJD in other persons born in Saudi Arabia. One previous case of vCJD, diagnosed by brain biopsy at the UCSF Hospital, University of California, San Francisco, and briefly described by the CDC, occurred in a person living in Virginia who was a non-Saudi Arabian national born and raised in Saudi Arabia [5]. That person's family recalled no history of travel to UK except for connecting flights. An earlier case of vCJD in 2003, never described in detail, affected a 33-year-old Saudi citizen who underwent brain biopsy at a hospital in Saudi Arabia; vCJD was diagnosed from a sample of the biopsy sent to the Mayo Clinic, Rochester, Minnesota, and confirmed by the National Prion Disease Surveillance Center, Case Western Reserve University, Cleveland, Ohio [1]; CDC noted that the patient "may have visited the UK, if at all, only for several days"

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

(although he had visited France) and concluded that he was most likely to have been infected in Saudi Arabia [5].

BSE in Saudi Arabia. Saudi Arabia has not reported any case of BSE to the World Organisation for Animal Health (OIE) [36]. BSE has very rarely been recognized in other countries of the general region: two cases of BSE were reported in cattle imported into Oman in 1989 [37] and one case in a native bovine in Israel was reported in 2002 [38]. However, Saudi Arabia was identified as having imported live cattle and beef products from the UK during the period of concern (1980-1996) [24], and Saudi Arabia was identified as a consignee of meat-and-bone meal (MBM) of UK origin, during the years 1988-1993 when MBM might have been contaminated with the BSE agent [23].

We have assumed, for the purposes of this analysis, that the major risk of human exposure to the BSE agent in Saudi Arabia was from beef and live cattle of UK origin exported to the region during the years of concern: 1980 through 1996. According to Sanchez-Juan and colleagues [24], the UK exported to Saudi Arabia almost 1,000 live bovines (1980-1990) and about 32,000 tons of carcass meat (1980-1996). Earlier estimates of exports reported by a representative of the World Health Organization (WHO) to TSEAC were roughly similar [23]. However, we cannot verify the accuracy of those figures. We have also assumed that exports of live cattle, beef, MBM and other bovine-derived products exports from the UK to Saudi Arabia ceased when the European Commission prohibited such exports both to Member States of the European Community and to "third countries" in March 1996 [16]. Furthermore, the UK implemented an enhanced prohibition of mammalian proteins in ruminant feed in 1996 and other controls to enhance the safety of food for humans and animal feeds by the end of 1996 [25]; therefore, we conclude that the risk of exposure to the BSE agent in any products and live cattle exported from the UK to Saudi Arabia after that time was small.

We acknowledge that other BSE countries (i.e., countries of Europe) might also have exported beef to Saudi Arabia and neighboring countries both during the years 1980 through 1996 and afterwards, however (1) the much lower rates of both diagnosed BSE and vCJD cases in other countries relative to the UK suggest that the risk associated with beef from those countries must be considerably less than for UK beef, and (2) we have not been able to estimate imports of beef from non-UK countries into Saudi Arabia. We are also unable to estimate cross-border sales of cattle or beef products in the region or the possibility that BSE might have been introduced into native ruminants in Saudi Arabia by the use of MBM—either imported or domestically produced—in animal feed supplements. Saudi Arabia is estimated to have had about half a million cattle in 1998 and far larger numbers of camels, goats, and sheep [2]. While acknowledging the theoretical possibility of BSE infections in local ruminants, we concluded that the risk of such infections is probably much less than that of beef products from the UK and too uncertain to consider unless and until reliable information becomes available.

Estimating the possible risk of dietary exposure to the BSE agent in US donors of blood and tissues during residence in Saudi Arabia. Since 1999, FDA's recommendations regarding deferral of blood and ineligibility of donors of HCT/Ps potentially exposed to the BSE agent in various countries—geographic deferrals—have been based on rough comparisons of the estimated risk of oral exposure to the BSE agent

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

in various groups of people compared to the risk of the UK population from the beginning of 1980 until the end of 1996, when UK food/feed protections were fully implemented. FDA, in 2001, announced a model that estimated the risk in most countries of Western Europe assigned as a relative-risk compared to the UK. The risk of dietary exposure to the BSE agent was assumed to be stochastic and directly (linearly) related to the time spent in a country where the BSE agent contaminated beef products [6]. In principle, the exposure of concern was consumption of beef products, but dietary histories were unavailable and are probably unreliable, so donor days in country were taken as a surrogate. Based on a number of other assumptions, the following relative risks were assigned: UK=1.0, France=0.05 (i.e., 5% of beef in France assumed to have been imported from the UK [3] and other countries of Western Europe=0.015 (extrapolating to the rest of Western Europe the results of intensive surveillance of BSE in Switzerland) [6]. For purposes of deferral policy, and in consideration of the absence of more detailed information, vCJD risk in Western Europe was taken as comparable to that in France as a worst case. A risk relative to UK of 0.35 was assigned to US military bases that obtained beef from the UK in various years using estimates of UK beef sourcing provided to the FDA by the US Department of Defense (DoD) [9]. These estimated relative risk factors are highly uncertain because of uncertain simplifying assumptions that underlie them. In fact, the model appears to have predicted fewer cases of vCJD than have been recognized in France (25 to date or more than 10% of the UK per capita rate) and overestimated cases in US military personnel and dependents (no cases to date among as many as 4.8 million active duty personnel and an unknown number of dependents and employees [32]). At the time, FDA also attempted to predict the possible loss of otherwise suitable blood donors that might result from various vCJD-related geographic donor deferral policies, based on a travel survey of donors in 12 blood centers [6]. Insofar as limited information has been available to us, we attempted a similar assessment of vCJD-related risk in Saudi Arabia, an assessment of reduction in that risk by donor deferral policies, and an estimation of the possible loss of otherwise suitable blood donors that might result.

1) **Estimates of relative prevalence of vCJD in various countries compared with Saudi Arabia.** We attempted to estimate vCJD risk in donors resident in Saudi Arabia by comparing the crude rate of vCJD attributed to residence in Saudi Arabia with rates for seven European countries currently on the FDA deferral list that have had cases attributed to infection within the country, not including three cases attributed to infection during residence in the UK [27]. Information to date, summarized in **Table 1,** suggests that the crude recognized prevalence of vCJD attributed to exposure to the BSE agent in Saudi Arabia to date (three cases in a total population estimated by the US Census Bureau earlier this year to be 26,132,000 [29]) resembles that in a number of European countries (somewhat lower than estimated prevalences in Ireland and France, both of which have lower rates than UK) for which FDA currently recommends geographic deferrals of blood donors [9] and screening of HCT/P donors [8]. It is important to note that the crude prevalence estimates provided in Table 1 have not been adjusted either for ages of the populations (younger persons being more often affected by vCJD than older persons) in the different countries or for probable differences in vCJD case recognition and reporting.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

2) **Potential consumption of UK beef products by persons resident in Saudi Arabia 1980-1996.** In trying to estimate exposure to UK beef products, we addressed two groups of residents.

(a) Estimated consumption of UK beef by the general population of Saudi Arabia, including Saudi nationals and foreign residents. We considered two factors affecting the risk of dietary exposure to the BSE agent: **(i)** estimated UK exports of beef to Saudi Arabia during the years 1980 through 1996, and **(ii)** estimated total beef consumption in Saudi Arabia. The latter adjustment was based on published data reporting that residents of Saudi Arabia, on average, consume considerably less beef than do residents of the UK and other Western European countries. Published sources suggested that about 10% of beef imported into Saudi Arabia during the years of concern might have originated in the UK [24] [31] and that average annual per capita beef consumption in Saudi Arabia was about a quarter of that in the UK (lamb and poultry being more popular) [2, 17, 30]. Taken together, these figures, although not validated and admittedly uncertain, suggested that a reasonable average relative risk estimate for dietary exposure to BSE agent in UK beef by persons resident in Saudi Arabia during the years 1980-1996 might be 0.025 (i.e., 0.10 x 0.25) that of persons resident in the UK during the same period and not unlike the risk previously estimated for most countries of Western Europe.

(b) US military personnel on bases in Saudi Arabia. We also considered information provided to FDA by the Armed Services Blood Program Office, DoD, about sources of beef supplied by the US Government to the US military personnel stationed in countries of the Arabian Peninsula during the years of concern (which include the years of the First Persian Gulf War). Information about military beef was taken from a recent DoD review of procurement records. Beef in field rations/"meals ready to eat" [MREs] during those years was all of US origin. However, an uncertain but possibly significant amount of the beef sold to and consumed by US military personnel living on US bases in Europe and Saudi Arabia after 1980 originated in the UK, though such procurement decreased after 1989. We cannot assume with confidence that the origin of beef consumed on US bases in Saudi Arabia differed significantly from that on European bases south of the Alps. Acknowledging the uncertainties, we therefore assumed that the risk of dietary exposure to the BSE agent for US military personnel living on bases in Saudi Arabia from 1980 through the end of 1996 was similar to that FDA previously assigned to US military living on European bases south of the Alps, taken to be about 35% of that for UK residents during the same period. Unlike US military stationed on European bases, no military dependents lived in Saudi Arabia. For the most part, US military contractors were not supplied with food by DoD, purchased their food locally—"on the economy"—and so are assumed to have shared the general dietary risk of exposure to the BSE agent with other residents of Saudi Arabia.

Canadian deferral of blood donors resident in Saudi Arabia. Since November 2007, Héma-Québec [21], a blood establishment operating in the Province of Quebec, has requested deferral of blood donors resident in Saudi Arabia for any period of six months

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

or more from 1980 through 1996 [20]. Since March 2011, Canadian Blood Services (CBS) has required the same deferral [19]. Canadian blood donor deferral policies for residents of Saudi Arabia do not include donors with history of blood transfusion in that country. **Table 2a** compares current Canadian and US blood donor deferral policies for vCJD risk. The policies, while similar, are not identical. We are not aware that any other country has recommended blood donor deferral for residents of Saudi Arabia.

Canadian assessments for determining suitability of donors of cells and tissues. Health Canada requires that travel information be collected for cell and tissue donors and some other questioning of donors or their proxies about vCJD risk factors. There are, however, no exclusion criteria based on risk factors associated with residence in or travel to specific geographic areas [19]. US donor screening recommendations regarding vCJD for donors of HCT/Ps are summarized in **Table 2b.**

FDA's proposed response to reports of three vCJD cases in individuals likely to have been infected with the BSE agent in Saudi Arabia. The reports of three cases of vCJD attributed to residence in Saudi Arabia has implications for US blood safety recommendations and for the safety of HCT/Ps, affecting the suitability of four groups of potential donors: US military personnel serving in Saudi Arabia, US guest workers who were military contractors supporting US forces in Saudi Arabia, other US guest workers employed as non-military contractors in Saudi Arabia and immigrants to the US who lived in Saudi Arabia, during the years 1980-1996. Saudi Arabia is not currently included on the list of countries for which FDA has recommended deferral/ineligibility of donors [9].

FDA is considering modifications to current suitability/eligibility recommendations to include donors of blood and blood components, including Source Plasma and HCT/Ps who spent any cumulative period of six months or longer as military personnel serving in Saudi Arabia from 1980 through the end of 1996. This recommendation is similar to the current recommendation to defer donors resident on US military bases in Europe during years when they were supplied with UK beef (comprising an estimated 35% of the beef supply through 1996 south of the Alps [9]). FDA is also considering modifications to current suitability/eligibility recommendations to include any other donors of blood and blood components, including Source Plasma and HCT/Ps who spent any cumulative period of five years or longer living in Saudi Arabia from 1980 through the end of 1996. This modification is similar to the current recommendation to defer donors resident in France, except that, because of continuing reports of BSE affecting native cattle in several European countries and a lack of reliable information regarding implementation of food safety measures and cross-border trade in beef products in Europe [7], FDA continues to consider the period of potential dietary exposure to the BSE agent for France and most other European countries (except UK) to extend to the present. We have assumed that the BSE risk for Saudi Arabia was associated with importation of live cattle and beef from the UK and that the risk became negligible at the end of 1996.

We acknowledge that Saudi Arabia might have imported live bovines and beef from other BSE countries after 1996 [2], but we have not included that assumption in developing the proposed recommendations. Saudi Arabian authorities have assured FDA that, since at least 1996, the Kingdom has prohibited the importation of live bovines and

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

beef products from countries reporting BSE to the OIE, as suggested by public sources [14]. As noted above, Saudi Arabia has reported no case of BSE to the OIE, and we assume that native Saudi cattle have probably not been infected. The likelihood that BSE infection was established in the substantial number of small ruminants (sheep and goats—far outnumbering cattle in Saudi Arabia [2, 17]) seems remote. We do not have information regarding rendering and animal feeding practices in Saudi Arabia (specifically on production of MBM and use of MBM in feeds) that would allow more reliable assumptions.

Potential impact on US blood supply and on HCT/P supply resulting from proposed deferral of certain blood donors or ineligibility of certain cell and tissue donors resident in Saudi Arabia during the years 1980-1996

We considered four potential at-risk groups that would be affected under the proposed recommendation for US donors with a history of residence in Saudi Arabia during the years 1980-1996. The groups include: **(1)** US military personnel; **(2)** US guest workers who were contractors to the US military; **(3)** US guest workers who were contractors but not for the US military; and **(4)** immigrants from Saudi Arabia to the US (both Saudi and non-Saudi nationals, regardless of current citizenship). **Table 3** below summarizes the predicted number of US donors and blood donations lost as a result of the proposed changes to recommendations for determining suitability of blood and plasma donors based on residence in certain countries. Because the more limited available information on donors and donations of HCT/Ps, FDA has not been able to analyze the possible impact of the proposed recommendation on the US supply of HCT/Ps.

US military personnel. Based on information provided to FDA by DoD, approximately 600,000 US troops were deployed to Saudi Arabia for a period ≥ 6 months in the years 1980-1996; that number represents about 90% of total deployments to Saudi Arabia during that period. Those persons would all be deferred from blood donations or ineligible to donate under the proposed geographic risk factor recommendations. However, DoD estimates that approximately 30% of this population are already deferred from donating due to the vCJD European deferral and other reasons. In addition, a large number of this population retired or left the military and may be donating to civilian blood collection facilities.

US military contractor guest workers. Information from DoD indicated that approximately 200,000 personnel including DoD civilians and contractors were employed in Saudi Arabia during the years 1980-1996. We assumed that all had cumulative stays of ≥ 6 months but less than 5 years. Under the proposed recommendation, they would not be deferred from donating blood and would remain eligible to donate HCT/Ps.

US non-military contractor guest workers. We assumed all US non-military guest workers who lived in Saudi Arabia during the years 1980-1996 had cumulative stays ≥ 6 months with an average length of stay of four years [10, 12, 13, 15, 22]. We further assumed that 30% of US guest workers lived in Saudi Arabia for more than 5 yr [10, 12, 13, 15, 22] and thus would be deferred from blood donation and ineligible to donate HCT/Ps under the proposed geographic BSE risk factor recommendations. The *Average Annual Number* of US guest workers in Saudi Arabia was estimated using data from the

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

US State Department on the number of registered US citizens in Saudi Arabia in 1999 [35]. We used these data for the year 1999, extrapolated and summed each year to derive the total number of US guest workers in Saudi Arabia during 1980 and 1996.

Immigrants. Our estimates assume that all immigrants from Saudi Arabia since 1985 had stayed for ≥ 5 yr in Saudi Arabia during the years 1980-1996, and they would be deferred from blood donations or ineligible to donate under the proposed geographic BSE risk factor recommendations. The *Average Annual Number* of persons emigrating from Saudi Arabia to the US from 1985 to the present was derived from Immigration Statistics 1989-2010 released by the US Department of Homeland Security [34]. Our estimates do not capture non-Saudi nationals immigrating to the US from Saudi Arabia as the last residence of record and thus may somewhat underestimate the number of donors and donations in this category that would actually be lost.

Donor loss calculation. We calculated blood donor loss based on the assumption that individuals who resided in Saudi Arabia during the years 1980-1996 have a 5% rate of donation [28, 33], which is the donation rate for the general US population. Our calculation for the potential loss of blood units assumes that each donor donates approximately 1.7 units of blood each year [33]. The estimated potential impact on US blood supply resulting from the proposed donor deferral recommendation is summarized in Table 3

Questions for TSEAC

Question 1. Do available data support the consideration by FDA to recommend deferring donors of blood and blood components, including Source Plasma, and to determine to be ineligible donors of HCT/Ps, who

a) spent six months or more cumulatively in Saudi Arabia as US military personnel from the beginning of 1980 through the end of 1996 or

b) otherwise spent more than five years cumulatively in Saudi Arabia from the beginning of 1980 through the end of 1996?

Question 2. Please discuss the likely contribution of those recommendations to the safety of the products involved and the possible impact on supplies of blood, blood components, plasma derivatives and HCT/Ps.

Question 3. Please comment on additional information that might better inform FDA's consideration of the proposed or any further safety measures.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Table 1.

Reported vCJD cases per estimated total population 2011

Country	vCJD Cases	Estimated* Population 2011	Crude Rate
UK	**175**	**62,698,362**	**$2.8x10^{-6}$**
Ireland	2	4,670,849	**$4.3x10^{-7}$**
France	24	65,102,719	**$3.7x10^{-7}$**
Portugal	2	10,760,305	**$1.9x10^{-7}$**
Netherlands	3	16,847,007	**$1.8x10^{-7}$**
Spain	5	46,754,657	**$1.1x10^{-7}$**
Saudi Arabia	3	26,131,703	**$1.1x10^{-7}$**
Italy	2	61,016,804	**$3.3x10^{-8}$**
Japan	1	126,475,664	**$7.9x10^{-9}$**

vCJD cases are attributed to exposure in a country according to the conclusion of the CJD Surveillance Unit, Edinburgh [27]. Cases resident for ≥ 6 mo in UK are attributed to UK. Rates are not adjusted for differences in population age profiles or for efficiency of case recognition and reporting in various countries.

*Population estimates for various countries were taken from the Web site of the US Census Bureau for mid-year 2011 [28].

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Table 2a

Comparison of Geographic vCJD-related Blood Donor Deferral Policies Recommended by FDA and Required by Canadian Blood Services

	USA FDA	Canadian Blood Services	Héma-Québec
UK	≥ 3 mo 1980-1996[a]	≥ 3 mo 1980-1996[b]	≥ 1 mo 1980-1996
France	≥ 5 yr 1980-present	≥ 3 mo 1980-96	≥ 3 mo 1980-96
Other Western Europe (WE)	≥ 5 yr 1980-present ≥ **28** countries[a]	≥ 5 yr 1980-present **12** countries[b]	≥ 6 mo 1980-present **12** countries[c]
Transfusion history	UK, France 1980-present	UK, France, WE 1980-present	UK, France, WE 1980-present
Saudi Arabia	no deferral	≥ 6 mo 1980-1996	≥ 6 mo 1980-1996
Other countries	no deferral	no deferral	no deferral

a US definition of United Kingdom = England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, and the Falkland Islands

US definition of WE (excluding UK, France) = Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Demark, Finland, Germany, Greece, Hungary, Republic of Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, and the Federal Republic of Yugoslavia ([sic] now Kosovo, Montenegro, and Serbia)

FDA also recommends deferral of US military personnel who spent ≥ 6 mo on certain military bases in Europe 1980-1996 [9]

b Canadian definition of United Kingdom = England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands (excludes Gibraltar and the Falkland Islands). Canadian definition of WE (excluding UK, France) = Austria, Belgium, Demark, Germany, Republic of Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Portugal, Spain, Switzerland

c http://www.hema-quebec.qc.ca/donner/don-de-sang/qui-peut-donner-du-sang/creutzfeldt-jakob.en.html

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Table 2b.

Geographic vCJD-related Cell and Tissue Donor Eligibility Policies Recommended by FDA

Ineligible Donors with history of	USA FDA
Residence in UK	≥ 3 mo 1980-1996[a]
Residence in Other Western Europe	≥ 5 yr 1980-present ≥ **28** countries[b]
Blood transfusion	UK, France 1980-present
Residence in Saudi Arabia	no current recommendation
Residence in Other Countries	no current recommendation

a US definition of United Kingdom = England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, the Falkland Islands

b US definition of Europe = Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Demark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom, Federal Republic of Yugoslavia ([sic] now Kosovo, Montenegro, Serbia)

FDA also recommends deferral of US military personnel who spent ≥ 6 mo on certain military bases in Europe 1980-1996 [8]

Note: Health Canada requires that travel information be collected and some donor other screening for vCJD-related risk factors. There are, however, no exclusion criteria for cell and tissue donors based upon risk factors associated with residence or travel history to specific geographic areas.

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

Table 3.

Estimated loss of blood donors and blood donations resulting from proposed recommendations to defer certain blood donors with history of residence in Saudi Arabia during 1980-1996

	US Military Personnel	US Guest Workers Military Contractors	US Guest Workers Non-Military Contractors	Immigrants to US	Total
Average annual number	n/a	n/a	36,000[a]	920[b]	n/a
Population to be deferred	420,000[c]	0[d]	45,900[e]	24,800[f]	490,000
Blood donors lost[g]	21,000	0	2,300	1,200	24,500
Blood units lost[h]	35,700	0	3,910	2,040	41,700

Notes:

[a]Average annual number of US guest workers in Saudi Arabia: based on data from US State Department for registered US Citizens living in Saudi Arabia in 1999 (http://overseasdigest.com/amcit_nu2.htm).

[b]Average annual number of immigrants from Saudi Arabia: based on data from US Department of Homeland Security, Yearbooks of Immigration Statistics 2004 and 2010 (http://www.dhs.gov/files/statistics/publications/yearbook.shtm).

[c]Number of military personnel to be deferred calculated by:
600,000 (total number of military personnel who stay for ≥ 6 months, DoD 2011) x 70% (percentage individuals having already been deferred, DoD 2011)

[d]Total number of military contractors who stay for ≥ 5 years, and thus to be deferred (DoD, 2011)

[e]Total number of US guest workers non-military contractors to be deferred calculated by:
(Average Annual Number of US guest workers x 17 years (from January 1, 1980 to December 31, 1996) / Average Length of Stay) x 30% (percent stay for ≥ 5years)

[f]Total number of immigrants to be deferred, calculated by:
Average Annual Number of immigrants x 27 years (from 1985 to current)

[g]Blood donors lost, calculated by:
Population to be deferred x 5% (donation rate)

[h]Number of blood units lost, calculated by:
Number of donors to be deferred x 1.7 (average number of donations per donor per year)

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

References

1. Belay ED, Sejvar JJ, Shieh WJ, Wiersma ST, Zou WQ, Gambetti P, et al. Variant Creutzfeldt-Jakob disease death, United States (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=16229761). Emerg Infect Dis. 2005;11(9):1351-4
2. Bourn D. Livestock Dynamics in the Arabian Peninsula. A Regional Review of National Livestock Resources and International Livestock Trade (http://ergodd.zoo.ox.ac.uk/download/reports/Livestock%20Dynamics%20in%20the%20Arabian%20Peninsula.pdf). FAO 2003
3. Brown P, Will RG, Bradley R, Asher DM, Detwiler L. Bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease: background, evolution, and current concerns (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=11266289). Emerg Infect Dis. 2001;7:6-16
4. Canadian Creutzfeldt-Jakob Disease Surveillance System, National Microbiology Laboratory, Public Health Agency of Canada. Variant Creutzfeldt-Jakob Disease in a Canadian resident. (http://www.phac-aspc.gc.ca/ccdrw-rmtch/2011/ccdrw-rmtcs1011r-eng.php#a1) Canada Communicable Disease Report. 2011;4(10)
5. CDC Website. Confirmed case of variant Creutzfeldt Jakob Disease (vCJD) in the United States in a patient from the Middle East (http://www.cdc.gov/ncidod/dvrd/vcjd/other/vcjd_112906.htm). 2010
6. Center for Biologics Evaluation and Research, United States Food and Drug Administration, Department of Health and Human Services. Deferral of blood donors potentially exposed to the agent of variant Creutzfeldt-Jakob disease (vCJD). Transcripts of the TSE Advisory Committee Meeting, Issue Summary. June 28, 2001 (http://www.fda.gov/ohrms/dockets/ac/01/briefing/3762b1_01.htm). 2001
7. Center for Biologics Evaluation and Research, United States Food and Drug Administration, Department of Health and Human Services. FDA's geographic donor deferral policy to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by blood and blood products and human cells, tissues and cellular and tissue-based products. Review of current FDA policies. Transcripts of the FDA TSE Advisory Committee Meeting, October 29, 2010 (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/TransmissibleSpongiformEncephalopathiesAdvisoryCommittee/ucm244062.htm). 2010
8. Center for Biologics Evaluation and Research, United States Food and Drug Administration, Department of Health and Human Services. Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), Aug 2007 (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm) 2007
9. Center for Biologics Evaluation and Research, United States Food and Drug Administration, Department of Health and Human Services. Guidance for Industry. Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products. May 2010 (http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM213415.pdf) 2010:1-41
10. Consulate General of India, Jeddah. Basic legal information of Indian workers in the Kingdom of Saudi Arabia. Compiled by Consulate/Embassy [of India] (http://www.cgijeddah.com/cgijed/publication/basiceng/complete.htm). 2011

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

11. Coulthart M, Phielip N, Jansen G, Morgenthau D, Kruse J, Sloan A, et al. Second case of variant CJD in Canada: case report and implications for assessment of geographic risk. PRION 2011. Abstracts (New World, Montréal, Québec, May 19, 2011). 2011

12. Dubai & Saudi Recruitment International Workforce Specialists DSR. Frequently asked questions (http://www.dubai-recruitment.com/faq.php). 2011

13. Dubai & Saudi Recruitment International Workforce Specialists DSR. South African and international workforce provider for employment in the Gulf countries (http://www.dubai-recruitment.com/reginfo.ph). 2011

14. Encyclopedia.com. Saudi Arabia. Animal husbandry (2005) (http://www.encyclopedia.com/topic/Saudi_Arabia.aspx). 2011

15. European Centre for Languages and Training. Al Rajhi Company for Human Resources Development. Teach English in Saudi Arabia (http://www.teachsaudi.50webs.com/terms.htm). 2011

16. European Commission. Commission decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy (http://www.neenar.com/europaenhancer/Enhancer.pl?ojref=CELEX:31996D0239:EN:HTML&ojpdf=OJ:L:1996:078:0047:0048:EN:PDF&format=). Official Journal of the European Communities. 1996;L78/47:2 pp

17. European Commission. DG Health and Consumers. Food and Veterinary Office Inspection Report Database. Mission to SaudiArabia. Report on a follow-up mission carried out to Saudi Arabia. 28 Aug- 4 Sept 1998 in the field of animal health with particular regard to equidae (Saudi Arabia 1998-1438). 1998; http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=516

18. Ghani AC, Donnelly CA, Ferguson NM, Anderson RM. Updated projections of future vCJD deaths in the UK. BMC Infect Dis. 2003;3:4

19. Health Canada. Frequently Asked Questions: [vCJD-related] Blood donation deferral policy expanded beyond Western Europe (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2011/2011_51faq-eng.php#a9). 2011

20. Héma-Québec. Annual Report 2007-2008. Labile blood products. Maintain a high level of product safety. Measures to ensure a high level of safety. Changes to donor selection criteria. Variant Creutzfeldt-Jakob disease (http://www.fda.gov/ohrms/dockets/ac/cber02.htm#TransmissibleSpongiform) 2008:5

21. Héma-Québec. Variant Creutzfeldt-Jakob Disease (vCJD). Donor selection criteria. Questions and answers (http://www.hema-quebec.qc.ca/donner/don-de-sang/qui-peut-donner-du-sang/creutzfeldt-jakob.en.html). 2011

22. Kingdom of Saudi Arabia. Ministry of Defence &Aviation. Saudi Arabian Armed Forces Medical Services Department. Al Hada Hospital and Rehabilitation Center & Prince Sultan Hospital (PSHRC). International employment contract (http://www.sais.8k.com/umgcont.html). 2011

23. Ricketts M. Efforts and needs for global control of BSE and vCJD. Presentation to Joint Meeting of FDA, TSE Advisory Committee and Blood Products Advisory Committee, January 17, 2002 (http://www.fda.gov/OHRMS/DOCKETS/ac/02/slides/3834s1.htm). Slides and transcript. 2002

24. Sanchez-Juan P, Cousens S, Will R, van Duijn C. Source of variant Creutzfeldt-Jakob disease outside United Kingdom (www.cdc.gov/eid/content/13/8/1166.htm). Emerg Infect Dis. 2007;13:1166-9

25. Soul P. BSE and human food chain protective measures in the UK . Transcripts of Joint Meeting FDA TSE Advisory Committee and Blood Products Advisory Committee, Jan 17, 2002 (http://www.fda.gov/ohrms/dockets/ac/cber02.htm#TransmissibleSpongiform). Transcript2002:159-97

Received by NSD/FARA Registration Unit 11/10/2011 4:49:19 PM

26. UK National Creutzfeldt-Jakob Disease Research and Surveillance Unit (NCJDRSU). Investigations undertaken in possible CJD cases. vCJD. Tonsil biopsy (http://www.cjd.ed.ac.uk/investigations.htm#vtonsil). 2011

27. UK National Creutzfeldt-Jakob Disease Research and Surveillance Unit (NCJDRSU). Variant Creutzfeldt-Jakob Disease. Current data. Update March 2011 (http://www.cjd.ed.ac.uk/vcjdworld.htm). 2011

28. US Census Bureau. International Programs. International data base (http://www.census.gov/population/international/data/idb/informationGateway.php). 2011

29. US Census Bureau International Programs. International database country rankings 2011 (http://www.census.gov/population/international/data/idb/rank.php). 2011

30. US Department of Agriculture. Foreign Agricultural Service. Beef: per capita consumption summary in selected countries (http://www.fas.usda.gov/dlp/circular/2006/06-03lp/bpppcc.pdf). 2006:20-2

31. US Department of Agriculture. Foreign Agricultural Service. Index Mundi. Saudi Arabia beef and veal meat production by year (http://www.indexmundi.com/agriculture/?country=sa&commodity=beef-and-veal-meat&graph=production). 2011

32. US Department of Defense. Directorate for Information, Operations and Reports. [Total deployments of US military to bases in the European Union 1980-1996] (www.dior.whs.mil/mmid/mmidhome.htm (accessed Mar 2005, no longer available July 2011). 2005

33. US Department of Health and Human Services. The 2007 National Blood Collection and Utilization Survey Report (www.hhs.gov/ophs/bloodsafety/2007nbcus_survey.pdf). 2007

34. US Department of Homeland Security. Yearbooks of Immigration Statistics. 2004 and 2010 (http://www.dhs.gov/files/statistics/publications/yearbook.shtm). 2011.

35. US Department of State. Registered US Citizens in Saudi Arabia in 1999 (http://overseasdigest.com/amcit_nu2.htm). 2011

36. World Organisation for Animal Health (OIE). Bovine Spongiform Encephalopathy (BSE). Geographical distribution of countries that reported BSE confirmed cases since 1989 (http://www.oie.int/en/animal-health-in-the-world/bse-specific-data/). 2011

37. World Organisation for Animal Health (OIE). Countries/territories having reported cases of BSE in imported animals only (http://www.oie.int/en/animal-health-in-the-world/bse-specific-data/cases-in-imported-animals-only/). 2011

38. World Organisation for Animal Health (OIE). Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide (excluding the United Kingdom) (http://www.oie.int/en/animal-health-in-the-world/bse-specific-data/number-of-reported-cases-worldwide-excluding-the-united-kingdom/). 2011